REMARKS

I. Formal Matters

A. Status of Claims

Claims 1-11 are pending in the application. Claims 1-4 are rejected. Claims 5-11 are objected to.

Claim 1 has been amended to recite the substituents for R^1 and R^2 as disclosed in the specification at least at page 5, lines 8-27.

Claim 1 has also been amended to recite the concentration range of the pyridone, as supported at least by the examples of specific compositions and by the compositions disclosed in Examples 1-11.

Claims 5, 6, and 8-11 have been amended to eliminate improper multiple dependencies. In addition, various obvious editorial and clerical amendments have been made to claims 2, 8, and 9-11.

No new matter is added.

B. Foreign Priority

The Examiner has not acknowledged Applicant's claim to priority nor receipt of the foreign priority document.

PAIR indicates that a copy of the priority document was supplied by the International Bureau on June 24, 2005.

Accordingly, the Examiner is requested to acknowledge Applicant's claim to priority and receipt of the priority document.

C. Information Disclosure Statement

The Examiner returned a copy of the PTO Form SB/08 that accompanied the Information Disclosure Statement filed June 24, 2005. However, the Examiner only initialed the US Patent reference. The Examiner pointed out that the listing of references in the Search Report is not considered to be an Information Disclosure Statement (IDS) complying with 37 C.F.R. § 1.98, in that legible copies of each foreign patent need to be submitted.

In order to have the references considered, the references, along with a second IDS and the $180 fee are being filed herewith.

II. Detailed Action

A. Claim Objections - 35 U.S.C. § 1.175(c)

1. Claims 5-11 are objected to under 37 C.F.R. § 1.175(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Appropriate amendments have been made to claims 3 and 5-11 to overcome this objection.

B. Claim Rejections - 35 U.S.C. § 112

1. Claims 1 and 3-4 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

According to the Examiner, Applicant has not provided any teaching as to what structural characteristics are needed to make the pyridone derivative soluble in high concentration in a solvent. Thus, the Examiner asserts that claim 1 should recite the specifically disclosed substituents R^1 and R^2.

The rejection is overcome by amending claim 1 to recite the substituents disclosed in the specification.

2. Claims 1-4 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

1) The Examiner asserts that the phrase "high concentration" is indefinite and the definition thereof in the specification of "more or less 25%" is also indefinite.

Claim 1 has been amended to replace the phrase "high concentration" with "a concentration of about 10% to about 25% by weight." Support is found at least in the examples of the specific compositions and in the compositions disclosed in Examples 1-11.

2) The Examiner asserts that because the claims recite that the composition contains an active ingredient, the claims should also recite what the active ingredient is effective for treating.

Claims 1 and 2 have been amended to delete reference to an active ingredient.

Accordingly, the Examiner is requested, respectfully, to reconsider and remove the rejections under 35 U.S.C. § 112.

C. Claim Rejections - 35 U.S.C. § 102

1. Claims 1-2 are rejected under 35 U.S.C. § 102(b) as being anticipated by Gadekar (U.S. Patent No. 3,839,346).

The Examiner asserts that since the phrase "high concentration" in claim 1 is indefinite, claims 1 and 2 include within their scope any composition comprising a pyridone of formula (I) in a solvent.

Gadekar does not disclose compositions in which the pyridone is present in a concentration of about 10% to about 25% by weight, as now recited in amended claim 1. Rather, Gadekar's only reference to a "concentration" is in Example 3, which teaches a therapeutic dose of a 1% composition of Gadekar's drug.

Accordingly, the rejection is overcome and should be removed.

2. Claims 1-4 are rejected under 35 U.S.C. § 102(e) as being anticipated by Scheiwe et al (U.S. Patent Publication No. 2006/0039931).

The Examiner's position is the same as that for Gadekar.

This rejection is improper, as Scheiwe is not legally effective prior art against the present application. Specifically, the Examiner relies upon the Sept. 11, 2003 international filing date of Scheiwe, which is prior to Applicant's international filing date of Dec. 24, 2003. However, 35 U.S.C. § 102(e) states that an international application only has the effect of an application filed in the United States if the international application designated the United States and was published in the English language. Applicant's research indicates that Scheiwe's international

application was published in the German language (see cover page submitted herewith). Accordingly, Scheiwe is only effective under 35 U.S.C. § 102(e) as of its actual United States filing date of March 11, 2005. Since this is after Applicant's international filing date of December 24, 2003, Scheiwe is not legally effective prior art against the present application.

Accordingly, this rejection should be removed.

D. Claim Rejections - 35 U.S.C. § 103

Claims 3-4 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gadekar (U.S. Patent No. 3,839,346) in view of Iyer et al (U.S. Patent Publication No. 2004/0033257).

Gadekar is applied as above to claims 1 and 2. Iyer is cited as teaching compositions comprising the diethylene glycol monoethyl ether solvent recited in claims 3-4.

For the following reasons, the rejection is traversed, respectfully.

Iyer teaches compositions comprising loratadine and diethylene glycol monoethyl ether. However, loratadine is not a pyridone as disclosed in Gadekar. There are structural differences between loratadine and the pyridones disclosed in Gadekar, such that one of ordinary skill in the art would not consider the compounds to have similar solubility characteristics.

Accordingly, one of ordinary skill in the art would not substitute the loratadine of Iyer for the pyridone of Gadekar.

In view of the above remarks, the Examiner is requested, respectfully, to reconsider and remove this rejection.

Reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

(54) Title: STABLE CREAM PREPARATIONS OF PHENYL-PYRIDONE COMPOUNDS FOR TOPICAL APPLICATION

(54) Bezeichnung: STABILE CREME-ZUBEREITUNGEN VON PHENYL-PYRIDONVERBINDUNGEN FÜR TOPISCHE ANWENDUNG

(57) Abstract: The invention relates to a pharmaceutical cream preparation for topical application in the form of an oil-in-water (o/w) emulsion, containing the following constituents in the lipophilic phase: (i) an optionally substituted 1-phenyl-2-(1H)-pyridone compound or a pharmaceutically acceptable salt thereof, as an active ingredient, (ii) at least one surface-active solubilising agent having an HLB value between 15 and 20, (iii) at least one emulsifier having an HLB value between 8 and 15, and (iv) optionally other carrier materials and additives known per se selected from the group containing triglycerides, penetration amplifiers, preserving agents and anti-oxidants. The invention also relates to the use of the preparation as a topical cream preparation for the treatment or prophylaxis of skin diseases.

(57) Zusammenfassung: Pharmazeutische Creme-Zubereitung für topische Anwendung in Form einer Öl-in-Wasser (o/w) Emulsion, welche in der lipophilen Phase die folgenden Bestandteile enthält: (i) als Wirkstoff eine gegebenenfalls substituierte 1Phenyl-2-(1H)-Pyridonverbindung, oder ein pharmazeutisch annehmbares Salz davon, (ii) mindestens einen oberflächenaktiven Solubilisator mit einem HLB-Wert im Bereich von 15-20, (iii) mindestens einen Emulgator mit einem HLB-Wert im Bereich von 8-15, sowie (iv) gegebenenfalls weitere an sich bekannte Trägermaterialien und Additive ausgewählt aus der Gruppe enthaltend Triglyceride, Penetrationsverstärker, Konservierungsmittel und Antioxidationsmittel; sowie Verwendung der Zubereitung als topische Creme-Zubereitung für die Behandlung oder Prophylaxe von Hauterkrankungen.

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